IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN THE MATTER OF THE ADMINISTRATIVE INSPECTION OF:	)	5:16M 1003
	)	CASE NO.
Precision Herbs 9804 Township Road 89 Killbuck, Ohio 44637	)	MAGISTRATE JUDGE BURKE
9227 Township Road 82 Millersburg, Ohio 44654	)	

AFFIDAVIT OF BENJAMIN J. DASTOLI

To the United States Magistrate Judge, United States District Court for the Northern District of Ohio:

Benjamin J. Dastoli, a duly authorized investigator in the Cincinnati District Office, United States Food and Drug Administration (FDA), United States Department of Health and Human Services, hereby applies for an administrative inspection warrant pursuant to the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 374, for the following establishments:

Precision Herbs
9804 Township Road 89
Killbuck, Ohio 44637

Precision Herbs
9227 Township Road 82
Millersburg, Ohio 44654

In support of this application, I, Benjamin J. Dastoli, make the following representations based on my personal knowledge of Precision Herbs and inspections thereof, as well as my review of official FDA records.

Precision Herbs Is Subject To FDA Regulation

1. Precision Herbs operates its business at 9804 Township Road 89, Killbuck, Ohio, within the jurisdiction of this Court. Precision Herbs's "Organization Head Office" is located at 9227 Township Road 82, Millersburg, Ohio, within the jurisdiction of this Court. Precision Herbs also has a website, www.precisionherbs.com (most recently accessed on October 22, 2015), which makes the following statements regarding its business, among others:

> Precision Herbs is a manufacturing business co-founded by Dr. and Mrs. Overman. Due to the death of Dr. James Overman on May 18, 2012, Precision Herbs is now owned and operated by Sharon Overman with the assistance of Dr. Eric Pierce. We manufacture over 600 herbal remedies, subtle energy devices and electronic devices. Our precision formulated herbal products are each specifically designed to accomplish one particular health goal as well as we possibly can. Our products have been formulated by Dr. James R. Overman, N.D., and Dr. Eric A. Pierce, N.D.

See Exhibit (Exh.) 1. The Precision Herbs website also states:

> If you know anything about alternative medicine, you know that the [American Medical Association], FDA, [Federal Trade Commission], and the pharmaceutical companies make life difficult for anyone who tries to manufacture, promote or sell anything, that actually helps people get well. They make so many laws that restrict what supplement manufacturers can do or say, that most supplements don't really do that much. We want to offer products that work extremely well, to actually fix numerous health problems.
>
> We have found a solution to that huge problem! Government agencies have a mandate to protect 'the public' but have very limited jurisdiction over 1st and 14th amendment, private membership associations. By being a private healthcare membership association, we are free to serve our members, with the help they so desperately need.

See Exh. 2.

Precision Herbs's Devices

2. Precision Herbs currently manufactures, processes, packs, holds, and/or distributes the following articles, and makes the following claims:

- Harmonic Combo ("[Has] the benefits of the Harmonic Quad HQ5 and the Harmonic Transmitter in one unit. . . . The Harmonic Combo effectively kills amoeba, bacteria, protozoa, viruses, mycoplasmas, slime molds, mildew, spirochetes, Nanobacteria, worms, flukes, and weaponized bacteria from biological warfare research. It also denatures prions by using the handhold feature. It is very effective for dealing with internal parasites throughout the body with the exception of inside the intestinal tract and inside cells," *see* Exh. 3);
- Electrolysis Foot Tub ("This device attaches to the leads of a Harmonic Quad 5 zapper. The device removes toxins from the body through the feet. . . . It is a great help to people with weak kidneys," *see* Exh. 4);
- Healing Detox Attachment ("If there are a lot of toxins inside the cells, it may take several hours to get them out. This not only takes them out of the cells, it also empowers the liver enzymes to detoxify them and remove them from the body," *see* Exh. 5); and
- Heart-Shaped Pocket Diode ("A diode is a small device made of composite material that protects you from electromagnetic frequencies from cell phones, cell phone towers, house electric wiring, appliances, fluorescent lights, TVs, transmission lines, transformers, radio waves, television waves, electric power substations, satellites, etc. It protects from damage by electromagnetic frequencies," *see* Exh. 6).

Because these Precision Herbs articles, among others, are intended for use in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body, and do not achieve their primary intended purposes through chemical action within or on the body and are not dependent upon being metabolized to achieve their primary intended purposes, they are "devices" as defined in the Act, 21 U.S.C. § 321(h).

3. As a device manufacturer, Precision Herbs is subject to FDA regulation under the Act's device provisions. Under the Act, devices are classified into one of three categories: Class I, II, or III. 21 U.S.C. § 360c. With certain exceptions not applicable here, devices — such as Precision Herbs's energy devices — that were not in commercial distribution prior to May 28, 1976 (the effective date of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539), are automatically classified as "Class III" devices as a matter of law and require premarket approval from FDA. 21 U.S.C. §§ 360c(f)(1), 360e(a). A recent search of FDA's CDRH Entry (CEntry) and electronic Center Information Retrieval System (eCIRS) databases revealed that there are no FDA-approved or cleared applications permitting the marketing of Precision Herbs's devices. Precision Herbs is also subject to FDA's device regulations including, but not limited to, the Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices regulations, 21 C.F.R. Part 807, and the Quality System Regulation, 21 C.F.R. Part 820. A recent search of FDA's Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM) revealed that Precision Herbs is not registered with FDA as a device manufacturer.

Precision Herbs's Drugs

4. Precision Herbs also currently manufactures, processes, packs, holds, and/or distributes the following articles with the following claims:

- Activase ("Historically used to activate the immune system to attack tumors, to aid other tumor-dissolving herbal products and to dissolve the protective protein coating from the surface of tumors so the body can attack them," *see* Exh. 7);
- Carcinogex ("[t]o remove carcinogenic chemicals from tumors," *see* Exh. 8); and
- C-Gene ("Historically used to inhibit cancer," *see* Exh. 9).

Because these Precision Herbs articles, among others, are intended for use in the cure, mitigation, treatment, or prevention of disease, they are "drugs" as defined in the Act, 21 U.S.C. § 321(g)(1). The articles are also "new drugs," as defined in 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for their labeled uses.

5. As a drug manufacturer, Precision Herbs is subject to FDA regulation under the Act's drug provisions. Under 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application is in effect for such drug or an investigational new drug application is in effect to permit such drug to be distributed for research purposes. A recent search of FDA's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) revealed that there are no FDA-approved applications permitting the marketing of Precision Herbs's drugs. Precision Herbs is also subject to FDA's drug regulations including, but not limited to, the Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution regulations, 21 C.F.R. Part 207, and the Current Good Manufacturing Practice (CGMP) in Manufacturing, Processing, Packing, or Holding of Drugs and CGMP for Finished Pharmaceuticals regulations, 21 C.F.R. Parts 210 and 211. A recent search of FDA's Electronic Drug Registration and Listing System (eDRLS) revealed that Precision Herbs is not registered with FDA as a drug manufacturer.

Precision Herbs's Foods (Dietary Supplements)

6. Precision Herbs manufactures, processes, packs, holds, and/or distributes the following as "Herbal Products," each which contain at least one dietary ingredient as that term is described in 21 U.S.C. § 321(ff)(1):

- Celery Seed 480 mg (contains celery seed), *see* Exh. 10;
- Wild Yam Root (contains wild yam root), *see* Exh. 11;
- Digestive (contains burdock leaf), *see* Exh. 12;
- Bone Build (contains bladderwrack), *see* Exh. 13; and
- Male Vitality (contains milk thistle herb), *see* Exh. 14.

These Precision Herbs articles, among others, are "dietary supplements," as that term is defined in 21 U.S.C. § 321(ff), and foods within the meaning of 21 U.S.C. § 321(f), *see* 21 U.S.C. § 321(ff).

7. As a food (dietary supplement) manufacturer, Precision Herbs is also subject to FDA regulation under the Act's food and dietary supplement provisions and FDA's food and dietary supplement regulations including, but not limited to, the Registration of Food Facilities regulations, 21 C.F.R. Part 1, Subpart H, Food Labeling regulations, 21 C.F.R Part 101, and the CGMP in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements regulations, 21 C.F.R Part 111. A recent search of FDA's Food Facility Registration Module (FFRM) revealed that Precision Herbs is not registered with FDA as a food facility.

8. FDA has the authority under the Act to enter and inspect any establishment in which devices, drugs, and/or foods (including dietary supplements) are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction. 21 U.S.C. § 374(a).

Precision Herbs's Regulatory History

9. On May 21, 2008, FDA's Cincinnati District Office sent a Warning Letter addressed to Dr. James Overman, then-President of Precision Herbs, L.L.C., at 9804 Township Road 89, Killbuck, Ohio, and Overman's Healthy Choices, Inc., at 9227 Township Road 82, Millersburg, Ohio, citing them for selling unapproved new drugs and misbranded drugs, including Activase and Carcinogex, on the website www.precisionherbs.com, in violation of the Act (hereafter, 2008 Warning Letter). *See* Exh. 15. Specifically, the 2008 Warning Letter stated that certain of the products were "drugs" within the meaning of 21 U.S.C. § 321(g)(1), because they were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. The 2008 Warning Letter further explained that these drugs were "new drugs" under 21 U.S.C. § 321(p), because they were not generally recognized as safe and effective for their labeled uses. The Warning Letter also explained that, under 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. The 2008 Warning Letter notified the firm that its drugs were also misbranded under 21 U.S.C. § 352(f)(1), because their labels failed to bear adequate directions for their intended uses.

10. By letter dated June 6, 2008, Dr. Overman responded to the 2008 Warning Letter, stating:

> These are the steps we are taking to assure that our products will be in full compliance with federal law:
>
> 1. The 15 products cited in your letter have been removed from the online store.
>
> 2. An order has been given to the employees that the 15 products in question not be manufactured or packaged until such time as the labels and literature can be made to comply with federal law.

> 3. We have started the process of reviewing all of our product labels, literature and website to bring our whole product line into full compliance with federal law.

See Exh. 16.

11. I and two other Investigators from FDA's Cincinnati District Office conducted an inspection of Precision Herbs's facility located at 9804 Township Road 89, Killbuck, Ohio, from September 24 - October 14, 2009 (hereafter, 2009 Inspection), in follow up to the 2008 Warning Letter. This was the first time FDA had inspected this Precision Herbs facility. During the inspection, we inquired about Overman's Healthy Choices, Inc., located at 9227 Township Road 82, Millersburg, Ohio, the other location to which the 2008 Warning Letter was addressed. Dr. Overman stated that he owned and operated a clinic at that location, where he saw clients and sold herbal products and devices. On October 1, 2009, Dr. Overman announced that he would not answer any more oral questions or provide any records without a written request.

12. While the 2009 Inspection was ongoing, Dr. Overman sent to FDA and/or provided to the FDA investigators numerous letters, including:

(a) a letter dated October 1, 2009, attached at Exh. 17, in which Dr. Overman said that "any and all manufacturing and sale of our products to the public has been terminated." The letter further stated that Precision Herbs "will fully comply with FDA statutes, regulations and orders in the future. We are also aware that your jurisdiction and authority is limited to the public domain, except for clear and present dangers of substantive evil per U.S. Supreme court decisions;"

(b) a letter dated October 1, 2009, attached at Exh. 18, noting FDA had "not presented a search warrant," invoking alleged First, Fourth, and Fifth Amendment rights under

the Constitution, and declining to answer any oral questions, but stating that any additional questions should be submitted in writing;

(c) a letter dated October 2, 2009, attached at Exh. 19, which purports to be an "official letter requesting a copy of the complaint and a request for a pre-administrative hearing;"

(d) a letter dated October 5, 2009, attached at Exh. 20, which was framed as "official notice" that FDA allegedly had "not complied with the Federal Privacy Act of 1974 (Title 5 U.S.C. § 552a)," which Dr. Overman believed "require[d] [FDA] to answer five (5) questions automatically before any inspection for information or data is provided to [FDA];"

(e) a letter dated October 5, 2009, attached at Exh. 21, giving "[n]otice of the Instant Pending Quasi-Criminal Proceeding and Lack of Fair notice by the FDA," and alleging that Dr. Overman "did not receive any prior notice that his conduct was even close to illegal or improper;"

(f) a letter dated October 5, 2009, attached at Exh. 22, which was framed as an "official request" that the FDA investigators who participated in the 2009 inspection at Precision Herbs and the FDA Compliance Officer identified in the 2008 Warning Letter, and "any other persons connected to this investigation," provide the firm with their "Oaths of Office;"

(g) a letter dated October 5, 2009, attached at Exh. 23, notifying FDA that the inspection was proceeding under "Extreme Duress and Protest" and requesting "a legal and proper Pre-Administrative Hearing;" and

(h) a "Notice to FDA Investigators," dated October 8, 2009, attached at Exh. 24, stating:

> You may not enter the premises unless you: 1.) Provide a copy of the official complaint founded upon probable cause. 2.) Provide a pre-administrative hearing. 3.) Provide proper answers to the Privacy Act and other required questions that must be responded to before the investigation begins. 4.) Declare this investigation to be quasi-criminal, not civil and the standard of review is clear and convincing evidence; not preponderance of evidence. 5.) Provide copies of oath of office and proof of filing for all officers and investigators involved in this case.

13. On December 1, 2011, FDA's Center for Devices and Radiological Health issued a Warning Letter to Precision Herbs, attached at Exh. 25 (hereafter, 2011 Warning Letter), citing the firm for marketing devices, including the Harmonic Combo, Electrolysis Foot Tub, Healing Detox Attachment, and Heart Shaped Pocket Diode, that are adulterated under 21 U.S.C. § 351(f)(1)(B), because the firm does not have approved applications for pre-market approval in effect for such devices pursuant to 21 U.S.C. § 360e(a), or approved applications for an investigation device exemption under 21 U.S.C. § 360j(g). The 2011 Warning Letter also stated that the devices are misbranded under 21 U.S.C. § 352(o), because Precision Herbs did not notify FDA of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

14. By letter dated December 7, 2011, attached at Exh. 26, Dr. Overman responded to the 2011 Warning Letter. The letter stated: "[T]he Private Healthcare Membership Association web site www.precisionherbs.com is a private membership association website of Precision Herbs, a Private HealthCare Membership Association." The letter further stated that "[i]f [the 2011 Warning Letter] is concerning our Private Membership Association then this letter is our official notice that your FDA Warning Letter concerning our private membership association is erroneous, illegal and bogus. Your agency has no jurisdiction, authority or legal standing to issue an FDA Warning Letter concerning the private membership association . . . ." *Id.*

15. Precision Herbs continues to introduce or cause the introduction of its FDA-regulated products into interstate commerce. *See* Exh. 27 ("As an added convenience, Precision Herbs ships worldwide, using FedEx as our main carrier"). Customers can buy products directly from Precision Herbs or its wholesalers.

16.

Redacted

17.

Redacted

Precision Herbs's Refusal to Permit FDA Representatives to Inspect, Access, Copy, and Verify Records

18. Investigator Edward R. Kay and I, both duly authorized investigators in FDA's Cincinnati District Office, arrived at Precision Herbs's facility located at 9804 Township Road

89, Killbuck, Ohio 44637, on March 23, 2015. We presented our FDA Credentials and issued an FDA Form 482, Notice of Inspection, to Eric Pierce, who identified himself as Precision Herbs's CEO, but not an owner of the firm. Investigator Kay and I explained that the purpose of our inspection was to follow up on the issues cited in FDA's 2011 Warning Letter.

19. Mr. Pierce refused to allow us to conduct our inspection. He stated that Precision Herbs was a private organization protected by Constitutional rights. Mr. Pierce gave us two documents. One document, attached at Exh. 33, states that the facility is a member of "Alternative Health Group," which is purportedly "[a] 1st, 5th and 14th Amendment Private Membership Association that contracts for services and benefits with private members only, not the public." That document further states that FDA may not enter the premises unless it "[p]rovide[s] a copy of the official complaint founded upon probable cause," and "[p]rovide[s]a pre-administrative hearing," among other things. The second document Mr. Pierce gave us, attached at Exh. 34, was a "Membership Contract" for "PRECISION HERBS (A Private Healthcare Membership Association)." Among other things, this documents states that "since the Association is protected by the First and Fourteenth Amendments to the U.S. Constitution, it is outside the jurisdiction and authority of Federal and State Agencies and Authorities . . . ." Mr. Pierce also told us that if FDA involved the United States Marshal in an attempt to inspect the facility, the local sheriff would be called to protect the company's rights.

20. Upon leaving the facility at 9804 Township Road 89, Killbuck, Ohio, Investigator Kay and I drove to the 9227 Township Road 82, Millersburg, Ohio address. We saw that the sign at this location read "Original Design Wellness Center." We observed that the firm looked operational, as there were several cars in the parking lot, including the vehicle that Mr. Pierce had been driving. We did not attempt to enter or inspect this facility.

21. When I returned to my office, I received via facsimile a letter dated March 23, 2015, from Eric A. Pierce (attached at Exh. 35). The fax cover sheet and the letterhead both state that Precision Herbs is "A Private Healthcare Membership Association" and identified the 9227 Township Road 82, Millersburg, Ohio address as Precision Herbs's "Organization Head Office." *See* Exh. 35. In the letter, Mr. Pierce stated:

> On March 23, 2015 at 9:25 two investigators from your office delivered an inspection notice to our property. This document is incorrect or delivered to the wrong location. Specifically it stated that the firm name is "Precision Herbs LLC." At the address listed for the firm there is no "LLC[.]" Precision Herbs is a private healthcare membership association and not an "LLC[.]" Please note this in your records and apply such to any further communication. "Precision Herbs LLC" does not exist.

Id.

Information Sought With This Warrant Application

22. FDA is charged with protecting the public health by ensuring, among other things, that "there is a reasonable assurance of the safety and effectiveness of devices intended for human use," "human [ ] drugs are safe and effective," and "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A)-(C). To carry out its public health mission, FDA must be able to: (1) evaluate the devices that Precision Herbs sells and determine whether the firm is complying with registration and listing requirements, premarket notification requirements, and the Quality System Regulation, and determine whether Precision Herbs's devices are being lawfully marketed under the Act. In addition, FDA must be able to evaluate device labeling, manufacturing, and distribution records to ensure that only devices that have received FDA premarket approval or clearance for their intended uses are distributed in interstate commerce; (2) evaluate the drugs that Precision Herbs sells and determine whether the firm is

complying with drug registration and listing, drug approval, and CGMP requirements for drugs, and determine whether Precision Herbs's drugs are being lawfully marketed under the Act. In addition, FDA must be able to evaluate drug labeling, manufacturing, and distribution records to ensure that only drugs that have received FDA approval for their intended uses are distributed in interstate commerce; and (3) evaluate the dietary supplements that Precision Herbs sells and determine whether the firm is complying with the food registration requirements, dietary supplement labeling requirements, and the dietary supplement CGMP regulations.

23. During the requested inspections, FDA will attempt to determine whether Precision Herbs is complying with the device registration and listing requirements and the Quality System Regulation, whether premarket approval or clearance is required before Precision Herbs can lawfully market its devices, and whether Precision Herbs is introducing or delivering for introduction into interstate commerce only legally-marketed devices. FDA will also attempt to determine whether Precision Herbs is complying with the drug registration and listing requirements and drug CGMP requirements, whether approval is required before Precision Herbs can lawfully market its drugs, and whether Precision Herbs is introducing or delivering for introduction into interstate commerce only legally-marketed drugs. FDA will also attempt to determine whether Precision Herbs is complying with the food registration requirements and the dietary supplement labeling requirements and whether Precision Herbs's dietary supplements are and manufactured in compliance with the dietary supplement CGMP regulations.

Request for a Warrant and Sealing Order

24. Therefore, pursuant to 21 U.S.C. § 374, FDA seeks an Administrative Inspection Warrant for entry to the Precision Herbs's facilities located at 9804 Township Road 89, Killbuck, Ohio, and 9227 Township Road 82, Millersburg, Ohio, for the following purposes: (1) to inspect

all pertinent equipment, finished and unfinished materials, containers, and labeling relating to Precision Herbs's devices, drugs, and foods (dietary supplements); (2) for Precision Herbs's drugs, to inspect all things therein (including records (paper and electronic), files, papers, processes, controls, and facilities)[1] bearing on whether drugs which are adulterated or misbranded within the meaning of the Act, or which may not be manufactured, introduced into interstate commerce, or sold; or offered for sale by reason of any provision of the Act, have been or are being manufactured, processed, packed, transported, or held in such facilities, or otherwise bearing on violation of the Act; (3) for Precision Herbs's devices, to have access to, and to copy and verify records required under 21 U.S.C. § 360i, such as those required by 21 C.F.R. Parts 807 and 820; (4) for Precision Herbs's foods (dietary supplements), to have access to and to copy and verify all records required to be kept pursuant to 21 C.F.R. Part 111; (5) to collect samples as deemed necessary by FDA; and (6) to take photographs or videography as deemed necessary by FDA.

Procedure for Inspection After Issuance of Warrant

25. If the warrant issues, FDA will conduct the planned inspections during ordinary business hours. FDA will begin the planned inspections, as soon as practicable, after issuance of the warrant and will complete the inspections with reasonable promptness, assuming full cooperation by Precision Herbs. FDA will present a written FDA 482, Notice of Inspection and appropriate credentials as required by 21 U.S.C. § 374(a)(1).

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[1] Pursuant to 21 U.S.C. § 374(a)(1), the inspection shall not "extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to th[e] Act), and research data (other than data relating to new drugs, antibiotic drugs, . . .and subject to reporting and inspection" and "data relating to other drugs . . . which in the case of a new drug would be subject to reporting or inspection under lawful regulations....)."

26. The FDA Investigator(s) may be accompanied by one or more duly authorized FDA Investigators, Special Agents, and/or local law enforcement officers, or a Deputy United States Marshal.

27. A return will be made to this Court within ten (10) business days after the FDA Investigator(s) completes the inspections.

Sworn to and subscribed by:

Benjamin J. Dastoli

BENJAMIN J. DASTOLI, Investigator
U.S. Food and Drug Administration

The above-named affiant personally appeared before me this 15th day of January, 2016, and upon oath stated that the facts set forth in this application are true to the best of his knowledge and belief.

Kathleen B. Burke

KATHLEEN B. BURKE
United States Magistrate Judge
Northern District of Ohio